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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/923,791	08/08/2001	David Hung	12.019011	9920

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CYTYC CORPORATION
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MARLBOROUGH, MA 01752

EXAMINER

WINKLER, ULRIKE

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/923,791

Applicant(s)

HUNG, DAVID

Examiner

Ulrike Winkler

Art Unit

1648

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,6-15 and 17-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6-15 and 17-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

RD

Art Unit: 1648

DETAILED ACTION

The Amendment filed March 24, 2005 in response to the Office Action of December 28, 2004 is acknowledged and has been entered. Claims 1, 2, 5-15, 17-20 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claim Rejections - 35 USC § 103

The rejection of claims 1, 2, 5-15, 17-20 under 35 U.S.C. 103(a) as being unpatentable over Love et al. (U.S.Pat. No. 6,221,622, IDS) and Makita et al. (Breast Cancer Research, 1991, IDS) in view of Sukumar et al. (U.S. Pat. No. 5,763,415), King et al. (JNCI, 1983, IDS), Noguchi et al. (American Journal of Pathology 1994), Gross G. (Intervirology 1997) and Androphy (Ciba Found. Symposium, 1986) **is maintained** for reasons of record.

Applicants' arguments have been fully considered but fail to persuade. Applicants' arguments are (1) that the same 103 rejection was overcome by the previous amendments to the claims. The prosecution history indicates that the examiner only for the purpose of using a different reference had withdrawn the prior rejection. After applicants pointed out that reference of Evron et al. was published after the earliest priority date of the instant invention was the rejection using the Evron et al. reference was withdrawn. At that point the prior 103 art rejection was reinstated and the office addressed the prior arguments made by applicants in view of the first combination of references. The second office action was not made final giving applicants an additional opportunity to amend the claims. Applicants' argument that the rejection should

Art Unit: 1648

remain withdrawn because of the prior amendment is not convincing. The examiner chooses rejections based on the best available prior art, in this case the Love et al. reference is found to be the best prior art.

(2) Applicants argument is that Love et al. does not teach an elongated lumen.

Applicants' argument is that an elongated lumen is singular and therefore cannot include a double lumen catheter. In response, this argument is not convincing because the term "comprising" allows for additional elements such as a second elongated lumen and still be within the scope of the claim. Applicants could indicated clearly in the claim that a double lumen catheter is not part of the invention by way of a negative limitation or by limiting the elongated lumen to a single elongated lumen catheter.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a single elongated lumen) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

(3) Applicants also argue that Love et al. does not teach the use of a single lumen catheter. This argument is not convincing because in Love et al. at column 2 lines 8-20, the reference teaches that the Love and Barsky prior art reference uses a single lumen catheter and that the prior art reference contemplated the double lumen catheter but did not actually use such a catheter in the reference. The purpose of the Love et al. patent was to improve over the prior art by the using a double lumen catheter indicating that the prior art only included the single elongated lumen catheter.

Art Unit: 1648

(4) Applicants arguments is that the alleged failing of Love et al. cannot be made up by Maikta et al. The argument is not convincing because Makita et al. teaches the aspiration of ductal fluid / sample using an outer cylinder, the “outer” cylinder when aspirating the sample is a single elongated lumen present in the breast duct. The “outer” cylinder is a 16 gauge Surflo intravenous catheter, since the only catheter present at the time the sample is collected it functions as a single elongated lumen and meets the instant claim limitation (see figure 3, step 5).

(5) Applicants argument is that King et al. does not teach detecting viral agent in the ductal fluid sample. Applicants’ argument is that King et al. looks at cells present in the duct fluid and thereby the reference teaches the use of tissue rather than fluid for the detection of the viral agent. In response to applicants argument the method set out in the instant invention uses the term comprising which does not limit the detection of the viral agent to only fluid because it can have additional elements present. The ordinary artisan would know that any fluid removed from a breast duct would contain not only liquid but also cells. Furthermore, the instant specification does not limit ductal fluid to the liquid portion. “The fluid from the breast duct can contain ductal epithelial cells, including cells of a stage considered to be precancerous or cancerous.” See instant specification page 6, lines 10-12. “Once ductal fluid is analyzed for one or more markers, the fluid may also be analyzed cytological to determine the cytological status of the ductal epithelial cells and other cells.” See instant specification page 7, lines 3-5. Based on the usage of what is encompassed by ductal fluid in the instant specification ductal fluid comprises cells from the breast duct. Therefore, applicants argument that the King et al. references actually analyses tissue and not fluid is not convincing because from the instant specification it is clear that cells are included in ductal fluid.

Art Unit: 1648

It remains the offices position that it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made based on the combination of references to identify the presence of papillomavirus in a single breast duct and apply treatment to the single breast duct. The invention remains rejected for the reason set forth above and those set forth in the prior office actions using the combination of references.

Claim Objections

The objection of claim 5 is withdrawn in view of cancellation of the claims.

Conclusion

No claims allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Papers related this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center. The faxing of


Art Unit: 1648

such papers must conform with the notice published in the Official Gazette, 1096 OG (November 15, 1989). The Group 1600 Official Fax number is: (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Tech Center representative whose telephone number is (571)-272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 571-272-0912. The examiner can normally be reached M-F, 8:30 am - 5 pm. The examiner can also be reached via email [ulrike.winkler@uspto.gov]. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 571-272-0902.


ULRIKE WINKLER, PH.D.
PRIMARY EXAMINER 6/9/25